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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,360	02/21/2002	Lawrence J. Bonassar	07917-137001 / UMMC 00-44	9677
26161	7590	09/20/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,360	<b>Applicant(s)</b> BONASSAR ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/2102.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/17/02&amp;3/18/03</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Claims examined on the merits are 1-18, which are all claims in the application.

Applicant is advised that should claim 14 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Document AF on form 1449 of 3/18/03 has been lined through since the document was previously listed on form 1449 of 6/17/02.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 13, 16, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of claim 4, it is uncertain as to material that is "pluronic". This term encompasses various different materials, and it is uncertain as to which is to be used. Additionally, this term appears to be a trademark and should be capitalized.

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In claim 13, the meaning of "CAD/CAM" is uncertain. This abbreviation should be replaced with the full name to be clear. Additionally, the meaning of "rapid prototyping" is uncertain.

Claim 16 is confusing and unclear by not having antecedent basis for "injection-molded". Claim 1 does not require injection when molding.

Claim 17 is unclear by requiring the hydrogel to be materials that are members of the Markush group recited since the materials are used to make the hydrogel rather than be the hydrogel. It is suggested that --- prepared from a material --- be inserted after "is" in line 1.

In line 2 of claim 18, "other cells that form cartilage" is uncertain as to cells that form and do not form cartilage.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art  
5 under 35 U.S.C. 103(a).

Claims 1-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (5,141,747) in view of Purchio et al (5,919,702) and Vacanti et al (6,171,610 B1) taken with Neefe (4,659,524), and if necessary in further view of Samuelsin (6,051,249)  
10 (all listed on form 1449).

The claims are drawn to making a construct for repairing a perforation in a tympanic membrane. The method contains steps of providing a negative mold having a negative shape of the construct, suspending isolated tissue precursor cells in a hydrogel to form a  
15 liquid hydrogel-precursor cell composition, introducing the composition into the mold, causing the composition to gel in the mold to form the construct, and removing the construct from the mold. Also claimed is using the construct to repair a perforation in a tympanic membrane.

20 Scholz discloses (col 2, lines 27-39) producing a collagen membrane by casting heated collagen molecules into a desired shape, such as a film, and then allowing the collagen to cool and gel. The gel is cross-linked to form the membrane. Cross-linking can result from dehydrating the gel (col 2, lines 38-39). The membrane can be

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used in tympanic membrane repair (col 2, lines 33-36 and col 5, lines 29-68).

Purchio et al discloses forming cartilage tissue for replacement of damaged cartilage tissue, which contains collagen (col 1, lines 36 and 44). Isolated chondrocytes are suspended in a hydrogel solution, such as prepared from polyphosphazines, polyacrylates or alginate which can be cross-linked with a divalent metal ion, (col 15, lines 1-45). The cell-containing hydrogel solution can be added to a mold and then hardened (col 14, lines 63-65) to form a matrix, which can be implanted to form new cartilage tissue. For creating tissue *in vitro*, cells are added to a matrix and then cultured *in vitro* to form the tissue (paragraph bridging cols 19 and 20).

Vacanti et al disclose forming tissue to replace damaged tissue by delivering a liquid hydrogel-cell composition, which contains a hydrogel and tissue precursor cells, into a support structure. As the composition solidifies, it takes the shape of the support structure, and new tissue is formed as the cells grow and multiply (col 1, lines 40-67, col 2, lines 21-65 and col 9, lines 5-22). The support structure can be polymer fibers, which can be compressed in a mold to form the desired shape (col 7, lines 44-50).

Neefe discloses making contact lenses using a negative mold. Heated soft resinous material is added to a convex negative mold having the shape of the lens such that the material assumes the shape of the mold, and allowing the material to cool and form a solid concave image of the mold (col 4, lines 12-35).

Samuelsen discloses using negative molding to produce a dressing by compression of a sheet of laminate between a positive and negative mold (col 9, lines 25-27 and 41-42).

It would have been obvious to substitute for the collagen  
5 membrane used by Scholz for tympanic membrane repair, tympanic  
membrane tissue produced by adding cells to a hydrogel solution  
followed by adding the solution to a mold of a desired shape, and  
gelling the hydrogel and culturing the cells as suggested by Purchio  
et al and Vacanti et al since the tissue produced in this manner would  
10 have been expected to provide the function of the collagen membrane  
and be superior to the collagen membrane by being more similar to  
tympanic membrane tissue. Using a negative mold to provide a desired  
shape would have been obvious when the shape desired is that formed by  
a negative mold as suggested by Neefe, and if needed as further  
15 suggested by Samuelsen. The conditions of dependent claims would have  
been matters of obvious choice in view of the disclosures of the  
references. The percentages of claims 6-8, concentration of claim 11  
and time of claim 13 are a matter of obtaining individual preferred  
conditions using limited routine experimentation, and would have been  
20 within the skill of the art. As to claim 16, injecting the cell-  
containing solution into the mold such as with a syringe would have  
been an obvious way of introducing the solution into the mold.

***Claim Rejections - 35 USC § 103***

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-12 and 14-18 above, and further in view of Abbott et al (AL on form 1449).

5       The claim requires preparing the negative mold using CAD/CAM or rapid prototyping.

Abbott et al discloses using computer-aided design or computer-aided manufacturing to producing a nylon model of traumatized mandible.

10       When using a negative mold as set forth above to produce tympanic membrane tissue, it would have been obvious to use a computer in construction of the mold as suggested by Abbott et al. Furthermore, the present specification discloses that computer hardware and software are available and can be employed using known techniques in  
15 the art (page 6, lines 23-25).

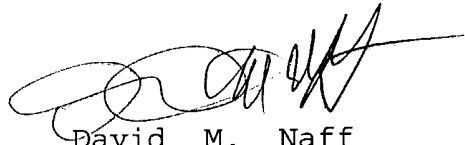
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be  
20 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
9/3/04